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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,919	11/08/2000	Samir Kumar Brahmachari	39562-175772	9079

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VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/10/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/707,919

Applicant(s)

BRAHMACHARI ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 21, 2002; June 13, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 and 16 is/are allowed.
- 6) ☒ Claim(s) 12-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to the papers filed June 13, 2002 and August 21, 2002. Currently, claims 12-14, 16 are pending.
2. The examiner thanks the applicants for the amendment filed August 21, 2002 which the examiner believed would place the claims in condition for allowance, however upon an interference search and further considerations, the examiner believes additional issues to unresolved. The examiner called applicant on August 29, 2002 to try to overcome these issues, however, it was agreed that it may be easiest to provide the issues in a communication.
3. This action contains new grounds of rejection.

Sequence Rules

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

For example, Figures 4-6 contain numerous sequences which are not identified by SEQ ID NO:.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claim 13 is rejected under 35 U.S.C. 102(a) as being anticipated by Choudhry and Brahmachari (SNP database, NCBI, rs695871 and rs695872 released August 2, 2000).

It is noted that the authorship of the Choudhry and Brahmachari reference is distinct from the inventorship of the instant application and that this rejection may be overcome by the filing of a 132 declaration.

As provided in Figure 4 of the instant application, the invention was known by others in this country before the invention thereof by the applicant for a patent. On page 4 and 7 of Figure 4, the authors appear to be Choudhry and Brahmachari.

Choudhry and Brahmachari teaches the G/C snp of the instant application. The release date for the SNP was August 2, 2000. The database also provides two primers

for amplifying the region containing the SNPs, namely SEQ ID NO: 1 and 2 of the instant application (page 6 of Figure 4). Moreover, in Figure 5, the T/C SNP of the instant application was disclosed on August 2, 2000. The database also teaches that SEQ ID NO: 1 and 2 of the instant application amplify the SNP.

Therefore, Choudhry and Brahmachari teach nucleic acids consisting of SEQ ID NO: 1 and 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Choudhry and Brahmachari (SNP database, NCBI, rs695871 and rs695872 released August 2, 2000) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

As provided in Figure 4 of the instant application, the invention was known by others in this country before the invention thereof by the applicant for a patent. On page 4 and 7 of Figure 4, the authors appear to be Choudhry and Brahmachari.

Choudhry and Brahmachari teaches the G/C snp of the instant application. The release date for the SNP was August 2, 2000. The database also provides two primers for amplifying the region containing the SNPs, namely SEQ ID NO: 1 and 2 of the instant application (page 6 of Figure 4). Moreover, in Figure 5, the T/C SNP of the

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instant application was disclosed on August 2, 2000. The database also teaches that SEQ ID NO: 1 and 2 of the instant application amplify the SNP.

The database entry does not specifically teach placing the primers in a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have primers for amplifying regions containing the SCA2 SNPs with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Choudhry and Brahmachari into a kit, as taught by Ahern for the express purpose of saving time and money.

Allowable Subject Matter

7. Claims 14, 16 drawn to methods of for predicting the risk of an individual to SCA2 are allowable over the art because the art does not teach nor suggest the claimed invention. While the database teaches each of these SNPs prior to the filing date of the application, the databases to not teach the haplotypes and association with increased or decreased risk of SCA2.

Conclusion

8. **Claims 14 and 16 are allowable over the art. Claims 12-13 are not allowable over the art.**

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
September 5, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600